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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)			
	10/593,136	JAIN ET AL.			
Office Action Summary	Examiner	Art Unit			
	Kevin S. Orwig	1611			
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	orrespondence address			
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period w.  - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tin vill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	I.  nely filed  the mailing date of this communication.  D (35 U.S.C. § 133).			
Status					
1) Responsive to communication(s) filed on <u>05 Ma</u>	action is non-final. nce except for formal matters, pro				
Disposition of Claims					
4) ☐ Claim(s) <u>26,32-35,41-43 and 45-55</u> is/are pend 4a) Of the above claim(s) <u>52 and 53</u> is/are with 5) ☐ Claim(s) is/are allowed.  6) ☐ Claim(s) <u>26,32-35,41-43,45-51,54 and 55</u> is/are 7) ☐ Claim(s) is/are objected to.  8) ☐ Claim(s) are subject to restriction and/or	drawn from consideration.				
Application Papers					
9) ☐ The specification is objected to by the Examiner 10) ☐ The drawing(s) filed on 18 September 2006 is lated Applicant may not request that any objection to the Replacement drawing sheet(s) including the correction 11) ☐ The oath or declaration is objected to by the Example 11.	are: a)⊠ accepted or b)⊡ objecd drawing(s) be held in abeyance. See ion is required if the drawing(s) is obj	e 37 CFR 1.85(a). ected to. See 37 CFR 1.121(d).			
Priority under 35 U.S.C. § 119					
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>					
Attachment(s)  1) Notice of References Cited (PTO-892)  2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  3) Information Disclosure Statement(s) (PTO/SB/08)  Paper No(s)/Mail Date 9/18/06.	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other:	nte			

### **DETAILED ACTION**

#### Status of the Claims

Claims 26, 32-35, 41-43, and 45-55 are currently pending. Claims 1-25, 27-31, 36-40, and 44 have been cancelled. Claims 26, 32-35, 41-43, 45-51, 54, and 55 are the subject of this Office Action. This is the first Office Action on the merits of the claims. Non-elected claims 52 and 53 are withdrawn from consideration.

#### Election/Restrictions

Applicants' election of Group I (claims 26, 27, 29, 32-35, and 41-51) in the reply filed on Oct. 27, 2008 is acknowledged. In response to applicant's election, Group II (claim 52) and Group III (claim 53) are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicants have elected Group I with traverse.

Three inventions were originally presented in this application: one drawn to a composition, one drawn to a method of making the composition, and one drawn to a method of using the composition. Group I is drawn to a different statutory category of invention (a composition of matter) than Groups II and III, which are drawn to processes (methods). While related by the claimed composition, the three inventions are not so closely related as to depend absolutely upon one another and are therefore patentably distinct. The traversal is on the ground(s) that Beerse (U.S. 6,294,186) does not break unity of invention. This traversal is not found to be persuasive because no specific reasons were provided as evidence that Beerse does not read on the claims. Rather,

applicants' argument consists of a restatement of portions of the instant specification describing various features of the instant invention. No specific statements refuting the evidence provided by the examiner in the restriction requirement have been presented.

Applicants have not shown that the groups of inventions have a general inventive concept under PCT rule 13.1. Unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features, meaning those technical features that define a contribution which each of the inventions, considered as a whole, makes over the prior art. As set forth in the restriction requirement mailed Aug. 27, 2008, the technical feature among the inventions is a pharmaceutical composition that comprises an active ingredient, a blend of surfactants, an oily component, and a stabilizing agent. However, Beerse in view of Larnier reads on the claims as amended. Hence, there is no technical relationship left over the prior art among the claimed inventions involving one or more of the same or corresponding special technical features, leaving two or more dependent claims without a single general inventive concept. Applicant is reminded that search burden is not relevant to unity of invention.

Thus, the restriction requirement is still deemed proper and is therefore made FINAL.

In the response of Feb. 19, 2009, claims 54 and 55 have been added and have been grouped with Group I. In the response, applicants elected the following species:

Active ingredient: terbinafine

Hydrophilic surfactant: polyoxyethylene sorbitan fatty acid ester

Lipophilic surfactant: sorbitan fatty acid ester

In the response, of Mar. 5, 2009, applicants elected the following species:

Other component: polyethylene glycol

It is noted that the response is still not in full compliance with the species election requirement since the elected surfactants do not represent *single* compounds as required in the species election requirement (see p. 3 of the notice of non-response dated Jan. 22, 2009). Rather polyoxyethylene sorbitan fatty acid esters and sorbitan fatty acid esters represent subgenuses of the claimed surfactants, each subgenus encompassing a large number of individual species. However, in the interests of compact prosecution, claims 26, 32-35, 41-43, 45-51, 54, and 55 will be examined further on the merits.

### Abstract

The abstract of the disclosure is objected to because of the following informalities: the word "fiend" in line two of the abstract should be amended. The examiner suggests replacing this word with "blend" or other suitable language. New matter is not permitted in the revised abstract. Correction is required. See MPEP § 608.01(b).

# Claim Objections

Claim 48 is objected to because of the following informalities: the phrase "wherein the topical formulation range from" should be "wherein the topical formulation is in the form of" to improve clarity of the claim language.

Appropriate correction is required.

# Claim Rejections - 35 USC § 112 (2<sup>nd</sup> Paragraph)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 26, 32-35, 41-43, 45-51, 54, and 55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

**A.** Claims 26, 32-35, 41-43, 45-51, 54, and 55 are indefinite in the recitation "enhanced localization of active ingredient" in claim 26. The term "enhanced" is a relative term which renders the claims indefinite. The term is subjective and is not defined in a limiting way in the specification. The term "enhanced" begs the question, "Enhanced relative to what?" This term is not defined by the claim, the specification does not provide a sufficient standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Thus, one of ordinary skill in the art could reasonably construe "enhanced" to be relative to any subjective measure. Since one of ordinary skill in the art could not be expected to make a reasonable distinction in the absence of further definitions and/or quidance in the specification, the metes and bounds of these claims are indefinite.

**B.** Claim 26 recites the limitation "the lipid microenvironment" in the last line of the claim. There is insufficient antecedent basis for this limitation in the claim as no lipid (and no lipid microenvironment) is recited previously in the claim. It is noted that the oily

component is not required to be a lipid, and could be, for example, mineral oil, which is not composed of lipids.

### **Priority**

The earliest effective U.S. filing date afforded the instantly claimed invention has been determined to be Mar. 17, 2005, the filing date of PCT application PCT/IN05/00086 to which the instant national stage 371 application claims priority.

Acknowledgment is made of applicant's claim to foreign priority under 35 U.S.C. 119(a)-(d). The certified copy of the Indian application was filed with the USPTO on Sep. 18, 2006. In the case that an intervening reference is applied in a rejection, applicants will be entitled to the foreign priority date for the purpose of overcoming the date of the reference, provided that a certified English language translation is supplied and it is determined that the corresponding foreign application supports the claims in the manner required by 35 U.S.C. 112, first paragraph. See MPEP § 201.15.

### Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.

- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 26, 32-34, 41, 43, 45-51, 54, and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over CHEN (U.S. 2002/0032171; Filed Jun. 8, 2001) in view of LARNIER (WO 02/078648; Published Oct. 10, 2002).

1. Chen discloses pharmaceutical compositions for improved delivery of therapeutic agents (abstract). The compositions may be in the form of gels and are useful for topical or transdermal administration of active agents (paragraphs [0024], [0116], [0162], and [0193]; claims 77, 157, 179, and 188). The compositions include a carrier formed from a triglyceride (i.e. an oily component), and at least two surfactants (i.e. a blend of surfactants) (abstract; paragraphs [0021]-[0023] and [0036]). The compositions also comprise an aqueous phase (abstract; [0027], [0032], [0152]). Chen

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discloses that the therapeutic agent may be hydrophobic and teaches the use of terbinafine HCl in the invention (paragraphs [0121] and [0145]).

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- 2. Chen teaches that at least one of the surfactants in the surfactant system should be hydrophilic (abstract), however Chen also teaches embodiments wherein both hydrophilic and a hydrophobic non-ionic surfactants are used (paragraphs [0022], [0023], and [0034]) and teaches that such mixtures are preferred (paragraph [0054]). Chen teaches that a hydrophobic surfactant is one that has an HLB value of less than 10, while a hydrophilic surfactant is one having an HLB value of greater than 10 (paragraphs [0051] and [0052]). Chen teaches that polyethylene glycol sorbitan fatty acid esters (elected species) such as various Tweens are preferred hydrophilic surfactants (paragraphs [0077]-[0078], [0099], [0100]; Table 12) and teaches that sorbitan fatty acid esters (elected species) such as various Spans are preferred hydrophobic surfactants (paragraphs [0090]-[0091], [0110], [0111]; Table 17). Chen also teaches that the composition preferably includes a mixture of two or more hydrophilic surfactants (paragraph [0054]), and teaches the preferred use of polyoxyethylene-polyoxypropylene block copolymers (i.e. Poloxamers), which are the preferred stabilizer of the instant invention (see paragraph [0038]). However, the difference between Chen and instant claims is that Chen does not explicitly embody the invention of claim 26 with sufficient specificity to be anticipatory. Since some picking and choosing of surfactants is required, this rejection is made under obviousness.
- 3. It is noted that "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third

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composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted) (Claims to a process of preparing a spray-dried detergent by mixing together two conventional spray-dried detergents were held to be *prima facie* obvious.). See MPEP § 2144.06. Furthermore, the MPEP states that the selection of known materials based on their suitability for their intended uses is also *prima facie* obvious. "Reading a list and selecting a known compound to meet known requirements is no more ingenious than selecting the last piece to put in the last opening in a jig-saw puzzle." 325 U.S. at 335, 65 USPQ at 301. See MPEP § 2144.07.

4. In the instant case, applicants are claiming a combination of known ingredients, all of which are taught by Chen, for the same purpose as that which has been taught in the art. Thus, in light of the teachings of Chen, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to combine preferred components (as taught by Chen) as instantly claimed per the teachings of Chen to produce a topical gel. Regarding the limitation that the surfactants act as gelators to form a network which immobilizes In light of these teachings, this limitation would be met when formulating Chen's composition as a gel. The MPEP states that, "The fact that appellant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious." *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). Furthermore, the MPEP states "The recitation of an additional

advantage associated with doing what the prior art suggests does not lend patentability to an otherwise unpatentable invention."

- Larnier discloses topical antimycotic compositions comprising terbinafine with 5. other agents (such as diclofenac or indomethacin) that improve the antimycotic properties of terbinafine (abstract; p. 1, last full paragraph; p. 2, last paragraph). Larnier teaches that the compositions of the invention are useful in gel form (p. 7, 1<sup>st</sup> paragraph and last full paragraph; Examples 1-7; claim 7). It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to select terbinafine as the active ingredient and to formulate Chen's compositions as gels, to provide a topical antimycotic in light of Larnier. One would have been motivated to do so with a high expectation of success since Chen teaches that the compositions may comprise terbinafine, diclofenac, and indomethacin (paragraphs [0126], [0138], and [0145]). Further, it is well within the skill of the ordinary artisan to select appropriate active agents to treat a given condition. Therefore if an artisan wanted to produce a topical antimycotic, one would have been motivated to use the combination of terbinafine and diclofenac or indomethacin to take advantage of the improved antimycotic properties as taught by Larnier and to use these actives in Chen's compositions to take advantage of the improved delivery of the therapeutic agents per Chen's teachings. Thus, claims 26 and 32-34, 47-50 are obvious over Chen and Larnier.
- 6. Regarding claims 41 and 54, Chen teaches that PEG-sorbitan monooleate is a preferred hydrophilic surfactant (paragraph [0078]) and teaches that sorbitan monooleate is a preferred hydrophobic surfactant (paragraph [0091]).

7. Regarding claims 43, 45, and 55, Chen teaches that the compositions may contain propylene glycol (elected species) as an additional component (paragraphs [0166], [0172], and [0239]; claims 56 and 57) and teaches that preferred triglycerides include medium chain triglycerides (paragraphs [0038] and [0199]; Example 4; claims 5 and 92).

8. Regarding claim 51, Chen teaches that other additives (i.e. excipients) such as preservatives, buffering agents, and colorants may be included in the compositions of the invention (paragraphs [0187] and [0188]).

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, in the absence of evidence to the contrary, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

Claims 35 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen in view of Larnier as applied to claims 26, 32-34, 41, 43, 45-51, 54, and 55 above, and further in view of BONNY (WO 01/54675; Published Aug. 2, 2001).

- 9. The teachings of Chen and Larnier are presented supra with respect to claims 26, 32-34, 41, 43, 45-51, 54, and 55. Chen generally teaches that the amounts of the surfactants will be determined by the artisan based on the characteristics of the composition (paragraphs [0020]-[0023] and [0150]-[0155]) and can be chosen by the artisan as desired (paragraph [0154]), but does not provide any actual weight values for the surfactants. Thus, to practice Chen's invention the artisan would have expected a routine amount of optimization for the amount of surfactant and would have looked to the literature for guidance.
- 10. Bonny discloses terbinafine pharmaceutical compositions that comprise a mixture of surfactants (title; abstract, p. 8, 4<sup>th</sup> paragraph). Bonny teaches that when a mixture of PEG-sorbitan monooleate (Tween-80) and sorbitan monolaurate (Span-20) is used, the weight ratio of the Tween and Span components is, for example 1:10 to 10:1 (p. 8, 4<sup>th</sup> paragraph). Bonny also teaches that the surfactant components may be present in amounts from 0.2 to 20% of the composition (p. 8, 5<sup>th</sup> paragraph). Thus, in combination with Chen and Larnier, the artisan would have easily arrived at the claimed amounts with no more than routine experimentation.
- 11. Regarding the claimed surfactant amounts, the MPEP states, "Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges

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by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, in the absence of evidence to the contrary, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

Claims 26, 32-34, 41, 43, 46-48, 50, 51, and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over BEERSE (U.S. 6,294,186; Filed Oct. 19, 1999) in view of LARNIER (WO 02/078648; Published Oct. 10, 2002).

12. Beerse discloses pharmaceutical gel compositions for topical administration that contain an antimicrobial or antifungal active ingredient (abstract; col. 8, lines 15-24; col. 20, lines 34-43). Beerse teaches the preferred use of a variety of surfactants including sorbitan fatty acid esters (e.g. SPANs) and polyoxyethylene sorbitan fatty acid esters (TWEENs) (col. 11, line 40 to col. 12, line 1). Beerse teaches the preferred use of mixtures of these emulsifying surfactants (col. 11, line 64 to col. 12, line 1), such as mixtures of surfactants having HLB values above and below 12 (col. 11, line 64 to col.

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12, line 1), which constitute a gelator system. Beerse teach the use of oily components including soy bean oil (i.e. a solvent system comprising at least one oily component) (col. 10, line 51). Beerse also teaches that the compositions contain an aqueous phase and preferably comprises a structuring agent that allows the compositions to form a gel network structure (col. 14, lines 41-45; col. 17, lines 34-40). Beerse teaches the use of propylene glycol (col. 36, line 28; Examples 6-13), celluloses and gums (col. 9, lines 60-65), and other components such as preservatives, colorings, and buffers (col. 14, lines 54-59). While Beerse teaches the use of antifungal agents (col. 20, lines 34-44), terbinafine is not specifically disclosed. However, the antifungal terbinafine was well known at the time of the invention.

13. For example, Larnier discloses topical antimycotic compositions comprising terbinafine with other agents (such as diclofenac or indomethacin) that improve the antimycotic properties of terbinafine (abstract; p. 1, last full paragraph; p. 2, last paragraph). Larnier teaches that the compositions of the invention are useful in gel form (p. 7, 1<sup>st</sup> paragraph and last full paragraph; Examples 1-7; claim 7). It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to select terbinafine as the active ingredient and to formulate Beerse's compositions as gels, to provide a topical antimycotic in light of Larnier. One would have been motivated to do so with a high expectation of success since Beerse teaches that the compositions may comprise antifungal agents as well as, diclofenac, and indomethacin (col. 33, lines 8-9 and 24-25). Further, it is well within the skill of the ordinary artisan to select appropriate active agents to treat a given condition. Therefore if an artisan wanted to

produce a topical antimycotic, one would have been motivated to use the combination of terbinafine and diclofenac or indomethacin to take advantage of the improved antimycotic properties as taught by Larnier and to use these actives in Beerse's compositions to take advantage of the enhanced antifungal effects of Beerse's compositions per Beerse's teachings. Thus, claims 26, 32-34, 41, 43, 46-48, 50, 51, and 55 are obvious over Beerse and Larnier.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, in the absence of evidence to the contrary, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

### Conclusion

Claims 26, 32-35, 41-43, 45-51, 54, and 55 are rejected. No claims are currently allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin S. Orwig whose telephone number is (571)270-5869. The examiner can normally be reached Monday-Friday 7:00 am-4:00 pm (with alternate Fridays off). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached Monday-Friday 8:00 am-

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5:00 pm at (571)272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KSO

/David J Blanchard/ Primary Examiner, Art Unit 1643